December 18, 2020

Contec Medical Systems Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District, BeiJing 102401
China

Re: K201980
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 16, 2020
Received: November 19, 2020

Dear Ray Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Alan M. Stevens -S3

CAPT Alan M. Stevens
Acting Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201980

Device Name
Infrared Thermometer

Indications for Use *(Describe)*
The TP500 Infrared Thermometer is intended to measure human body temperature by measuring from 1-3cm distance to the forehead. The device can be used on people of all ages. It is recommended that the device be operated by an adult. The device is intended to be used in the hospital and other clinical environments.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab #4 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K201980

1. Date of Preparation: 12/18/2020

2. Sponsor Identification

Contec Medical Systems Co., Ltd.

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Infrared Thermometer
Common Name: Infrared Thermometer
Model(s): TP500

Regulatory Information

Classification Name: Clinical electronic thermometer
Classification:II
Product Code:FLL
Regulation Number: CFR 880.2910
Review Panel:General Hospital;

Indication for Use Statement:

The TP500 Infrared Thermometer is intended to measure human body temperature by measuring from 1-3cm distance to the forehead. The device can be used on people of all ages. It is recommended that the device be operated by an adult. The device is intended to be used in the hospital and other clinical environments.

Device Description

The Infrared thermometer (model TP500) is a hand-held, battery powered, electronic thermometer that converts a subject's forehead temperature, using the infrared energy emitted in the area around the subject's forehead to an oral equivalent temperature when measured from 1-3cm to the center of the subject's forehead with no contact. The device can be used on people of all ages and is intended to be used in the hospital and other clinical environments.

The Infrared thermometer has the following features

① Non-Contact Design.
② One-button operation.
③ Quick to get data for just 1 second.
④ Memory function; Memory recall of 30 reading.
⑤ Switching between mute and un-mute.
⑥ Switching between Fahrenheit and Celsius.
⑦ Power management: automatic shutdown, low power consumption control; power display; low power reminder
⑧ Automatically power-off, if left idle for 5 seconds.
⑨ Prompt for 37.6℃ (99. 6 ℉) high temperature.

5. Identification of Predicate Device(s)

Primary Predicate Device
510(k) Number: K182597
Product Name: Infrared thermometer
Model Name: PG-IRT1602
Manufacturer:
Shenzhen Pango Electronic Co., Ltd

6. Non-Clinical Test Conclusion

The test results demonstrated that the proposed device complies with the following standards:

a. ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
b. IEC 60601-1-2 Edition 4.0 2014-02, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests.
c. ISO 80601-2-56 Second edition 2017-03 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)].
d. ASTM E1965-98 (Reapproved 2016) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
e. ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
f. ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization

The software verification and validation were conducted in accordance with the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," dated May 11, 2005. The test results demonstrated the software function met the requirements.

7. Clinical Test Conclusion

Controlled human clinical studies were conducted on proposed device with predicates in accordance with ASTM E1965-98, clinical bias, clinical uncertainty and clinical repeatability have been evaluated per clinical validation for infrared thermometer. The clinical trial results verify that the clinical accuracy of the proposed device is not inferior to that of predicate device.
Total 108 subjects and three age groups, including age 0~1 (35 subjects), age 1~5 (33 subjects) and age above 5 (40 subjects) are included in each clinical study, including febrile and afebrile persons.

The statistical results of clinical bias and clinical repeatability of two comparison groups were assessed and the results of the proposed device meet the performance parameters claimed in user manual, and the proposed device complies with ASTM E1965-98.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device(s) K201980	Predicate Device(s) K182597	Remark
Device name	TP500 Infrared Thermometer	PG-IRT1602 Infra-red Ear Thermometer	SE
Classification Name	Clinical electronic thermometer	Clinical electronic thermometer	SE
Product Code	FLL	FLL	SE
Regulation Number	CFR 880.2910	CFR 880.2910	SE
Comparison Statement	**The proposed device has same classification information as the predicate device.**		
Indications for Use	The TP500 Infrared Thermometer is intended to measure human body temperature by measuring from 1-3cm distance to the forehead. The device can be used on people of all ages. It is recommended that the device be operated by an adult. The device is intended to be used in the hospital and other clinical environments.	PG-IRT1602 Infrared Forehead Thermometer is intended to measure human body temperature by measuring forehead. The device can be used on people of all ages.	Analysis 1
Principle of Operation	Non-contacting, Infrared Temperature Measurement	Non-contacting, Infrared Temperature Measurement	SE
Comparison Statement	**The proposed device has a similar indication for Use and the same Principle of Operation as the predicate device.**		
Main Unit Technical Specifications			
Measurement Range	32℃～43℃（89.6℉~ 109.4℉）	34. 0℃-43.0℃	Analysis 2
Accuracy	±0.3℃（0.5℉）	±0.2℃ at 35.0 ℃-42.0℃ Others ±0.3℃	Analysis 2
Measurement	1-3cm	3~5cm	Analysis 2

distance			
Activation	Scan button	Scan button	SE
Power requirements	Two pieces of 1.5V AAA (number seven) batteries	Two pieces of 1.5V AAA (number seven) batteries	SE
Measurement Site	Forehead	Forehead	SE
Measuring interval	About 1 s	About 2 s	Analysis 2
Scale selection	℃/℉	℃/℉	SE
Display screen	LCD	LCD	SE
Display Resolution	0.1℃/0.2℉	Not Available	Analysis 3
Measurement Mode	Adjusted	Adjusted	SE
Reference Body Site	Oral	Not Available	Analysis 3
Operational Environmental conditions	16℃～40℃（60.8℉-104.0℉）; ≤ 95 % (no condensation); 70kPa～106kPa	Not Available	Analysis 3
Storage Environmental conditions	-20℃～55℃（-68.0℉-131.0℉）; ≤ 95 % (no condensation); 50kPa～106kPa	Not Available	Analysis 3
Intended Use Environment	Professional Healthcare Environment	Not Available	Analysis 4

Temperature ranges used for the identification of “Body Temp Lo” and “Body Temp Hi”	When the temperature measured is less than or equal to 32.0℃ (89.6℉), displays “Body Temp Lo”; When the temperature measured is greater than or equal to 37.6℃ (99.6 ℉) and less than 38.4℃, it displays “Body Temp Hi” and the screen backlight is yellow; When the temperature measured is greater than 38.4℃ (101.1℉), it displays “Body Temp Hi” and the screen backlight is red.	Not Available	Analysis 5
Memory	Save last measured 30 sets memories	9 sets	Analysis 2
Fever Prompt	Yes	Yes	SE
Back light	Yes	Yes	SE
Auto power-off	5 seconds after no operation	Auto shut off: 30 seconds without operation	Analysis 2
Sterile	No	No	SE
Single Use	No	No	SE
Materials	PC, white ABS, gray ABS	Not Available	Analysis 6
Comparison Statement:	**The proposed device has the similar main unit specifications with the predicate device and for those characteristics not available, the subject device meets applicable standards.**		
Applied Standards:			
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10	SE
Electrical Safety	IEC60601-1	IEC60601-1	SE
EMC	IEC60601-1-2	IEC60601-1-2	SE
Performance	ISO 80601-2-56	ISO 80601-2-56	SE

	ASTM E1965-98	ASTM E1965-98	
Comparison Statement	**The proposed probe has same applied Standards with the predicate device.**		

9. Substantially Equivalent (SE) Conclusion

The subject device has same classification information, similar indication for use, similar product design, similar specification, similar applied Standards as predicate device.

The differences are included as followings:

Analysis 1：The proposed device and predicate device are similar in the Indication for Use, with the proposed device being more specific in its indications. The differences do not raise new questions of safety or effectiveness and are evaluated through the testing.

Analysis 2：The Measurement Range, Accuracy, Measurement distance, Measuring interval, Memory, and Auto power-off are similar with the predicate device, both of them meet the requirement of safety and essential performance ISO 80601-2-56. The differences between the predicate device and subject device will not affect the effectiveness and safety of the subject device.

Analysis 3：The Display Resolution, Reference Body Site, Operational and Storage Environmental Conditions, cannot be compared to with the predicate device since these characteristics of the predicate device are not available; however, the subject device meets the requirement of safety and essential performance ISO 80601-2-56. These characteristics will not affect the effectiveness and safety of the subject device.

Analysis 4: The Intended Use environment is similar to the predicate but limited to only the Professional Healthcare Environment. This limitation in Intended Use Environment will not affect the effectiveness and safety of the subject device since the subject device passes IEC60601-1-2 related to its specific usage environment.

Analysis 5: The Temperature ranges used for the identification of “Body Temp Lo” and “Body Temp Hi”, are not available for the predicate device and cannot be compared with the subject; however, the subject device passes the software validation and the ranges presented will not affect the effectiveness and safety of the subject device.

Analysis 6: The materials used cannot be compared to the predicate device since these are not available; however, the materials of the subject device pass the necessary biocompatibility testing per ISO10993-5 and ISO10993-10 and the materials are shown to not affect the effectiveness and safety of the subject device.

Conclusion: Based on the safety and performance testing and compliance with acceptable voluntary standards, we believe that the Infrared Thermometer (Model TP500) is Substantially Equivalent (SE) to the predicate device (K182597) which is a legally marketed device and does not raise any new safety and effectiveness issues.